

REMARKS

This paper is presented in response to the Patent Office's July 19, 2011, letter indicating the applicants' "Amendment 'F'" filed July 5, 2011, is not fully responsive to the Patent Office's final action dated October 26, 2010.

Specifically, the Patent Office has taken the position that the method claims presented in the applicants' "Amendment 'F'" are "independent or distinct from the invention originally claimed for the following reasons: the originally presented claims were directed to a plasma sterilization indicator, not a method. There were no method claims in the application at the time of Final Rejection." Further, the Patent Office states that "[t]he indicator would not necessarily need to be used in the presently claimed method, thus providing the requisite rationale for restriction."

For the reasons explained below, the applicants respectfully disagree and respectfully request the Patent Office reconsider its position relative to the newly presented method claims.

Claims 1-19 have been canceled. New claims 20-23 are presented for examination. New claim 20 is written in independent form and recites a method that employs the same indicator that was the subject of the Patent Office's final action dated October 26, 2010. New claims 21-23 mirror claims 2-4, but have been presented as method claims depending from new claim 20. The foregoing amendments *do not* introduce new matter into the application or into the claims.

Contrary to the Patent Office's assertion, an indicator must be used in the recited method. For the convenience of the ensuing discussion, new claim 20 and previously examined and rejected claim 1 are presented in the table, below:

| New Claim 20 | Now-Canceled Claim 1 as of Oct. 26, 2010 |
|--|---|
| <p>A method comprising:</p> <p>providing a plasma-sterilization indicator comprising at least one compound (A) selected from the group consisting of adsorption indicators and metal chelate-titration indicators; an organic metal compound (B); and a polyvalent alcohol (C);</p> <p>forming a product via a cation in a reaction between the one or more compounds (A) and the organic metal compound (B); and</p> <p>discoloring the product by hydrogen peroxide plasma-sterilization,</p> <p>wherein:</p> <p>the polyvalent alcohol (C) increases a discoloration speed of the discoloring of the product,</p> <p>the absorption indicator is selected from indicators</p> | <p>A plasma-sterilization indicator, comprising:</p> <p>one or more compounds (A) selected from the group consisting of adsorption indicators and metal chelate-titration indicators; an organic metal compound (B); and a polyvalent alcohol (C),</p> <p>wherein a product formed in a reaction between the one or more compounds (A) and the organic metal compound (B) discolors into a different color in a particular pH range owing to a pH change caused by a hydrogen peroxide and an oxidative force in plasma treatment;</p> <p>wherein</p> <p>the adsorption indicator is selected from indicators</p> |

| New Claim 20 | Now-Canceled Claim 1 as of Oct. 26, 2010 |
|---|---|
| <p>used in detection of metal ions that discolor as upon adsorption on colloidal particles, and</p> <p>the metal chelate-titration indicator is selected from the group consisting of organic colorants having a proton that can be replaced with a metal ion in the molecule and compounds having multidentate ligands that can form a chelate compound by binding to a metal ion.</p> | <p>used in detection of metal ions that discolor as adsorbed on colloidal particle, and</p> <p>the metal chelate-titration indicator is selected from the group consisting of organic colorants having a proton that can be replaced with a metal ion in the molecule and compounds having multidentate ligands that can form a chelate compound by binding to a metal ion.</p> |

The action cites MPEP § 821.03 (which in turn quotes 37 CFR § 1.145) as support for the Patent Office's position. However, section 1.145 specifically states that the restriction is appropriate if, after an official action, the applicant "presents claims directed to an invention distinct from and independent of the invention previously claimed."

The Patent Office has not articulated facts sufficient to support a conclusion that the recited method is distinct from and independent of the previously-claimed device (indicator). The plain language of the method claims recites the use of the device (indicator). Specifically, the first step in the method is to "provid[e] a plasma sterilization indicator" comprising compounds A, B, and C. The second step is to form a product from the reaction of compounds A and B, and the third step is to discolor the product by sterilization. The method is not independent of the device (indicator); but, instead, requires the provision of the device to form and discolor a product.

Accordingly, there is no basis upon which the Patent Office may continue to assert that the recited method is subject to restriction from the previously-presented indicator claims. Reconsideration is respectfully solicited.

In the Patent Office's October 26, 2010, final action, indicator claims 1-3, 7, 10 and 11 were rejected under 35 USC § 103(a) as being obvious over Patel (WO 00/61200) in view of Kirckof (US 6,488,890), and claim 12 was rejected under § 103(a) as being obvious over Patel in view of Kirckof and Schmidt (US 2002/0155224).

As amended here, the invention is directed to a method that employs the previously-claimed indicator. In the recited invention, discoloring occurs according to an entirely different mechanism from that of Patel. Specifically, as recited in claim 20, a product formed in a reaction between one or more compounds (A), the organic metal compound (B) discolors into a different color in a particular pH range owing to a pH change caused by hydrogen peroxide and an oxidative force in plasma treatment, and a metal ion which is a cation participates in the reaction.

The October 26 action recognizes that in the reactive species disclosed in Patel are bromine anions, whereas in the pending claims, the reactive species is a cation (metal ion).

However, the amended claims do not recite a particular ion as a reactive species; therefore, independent claim 20 recites a method distinguishable from what is disclosed in Patel.

Further, in Patel, reactive species, which are anions such as a bromine anion, a chlorine anion, or the like, are generated from an activator by exposing the activator to oxidative plasma. The generated reactive species attach to the substrate dye, and thereby a color changeable indicator is produced, and discoloration based on the color changeable indicator occurs effected with a pH, as shown in the last line on page 6 to line 6 on page 7 of Patel.

The color change mechanism of Patel is also entirely different from that of the invention. Therefore, even if the same dye and aluminum chelate as the invention were to be used in Patel, a compound thereof after a color change would be entirely different from that of the invention.

Kirckof (US 6,488,890) describes a sterilization indicator system that allows a sterilization cycle to be monitored without the need for a user to subjectively distinguish between color, quality, or intensity of display patterns. However, the indicator does not fall within the scope of the invention, and an organic metal compound (B) defined in the specification and the reaction mechanism discussed above are not taught therein. Further, the concept of enhancing discoloration speed by a glycol solvent in the plasma-sterilization indicator composition is also not taught in Kirckof.

Schmidt (US 2002/0155224 A1) describes a thermal ink jet ink composition for textile media, which comprises a water miscible organic solvent, water, and a dye. However, a plasma-sterilization indicator itself or a plasma-sterilization indicator comprising one or more compounds (A) selected from the group consisting of adsorption indicators and metal chelate-titration indicators; an organic metal compound (B); and a polyvalent alcohol (C), in addition to the reaction mechanism or the concept of enhancing discoloration speed by a glycol solvent discussed above are not taught or suggested in Schmidt.

Thus, Kirckof and Schmidt neither teach nor suggest the subject matter of the invention, especially the technical features discussed above, and do not compensate for the deficiencies in Patel relative to the pending claims.

In consideration of the above, even if the teachings of Patel were considered in view of Kirckof, or in view of Kirckof and Schmidt, a person skilled in the art could not have achieved the subject matter claimed. Accordingly, the invention is not obvious over the disclosure of Patel in view of Kirckof, or in view of Kirckof and Schmidt.

CONCLUSION

In view of the foregoing, the applicants respectfully request cancellation of all previously-pending claims (i.e., claims 1-19), entry of new claims 20-23, reconsideration and withdrawal of the outstanding rejections, and allowance of all pending claims 20-23.

Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to contact the undersigned attorney.

Respectfully submitted,

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